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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,188	02/20/2001	John F.T. Conroy		3777

7590 10/15/2002

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EXAMINER
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NAFF, DAVID M

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/15/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/785788	Applicant(s) Conroy et al.
Examiner Hoff	Group Art Unit 1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

Responsive to communication(s) filed on 7/24/02

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

Claim(s) 1-34 is/are pending in the application.

Of the above claim(s) 1-14 + 27 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 15 - 26 + 28-34 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). 2-4 + 8 Filed 2/20, 5/28, 6/14, 10/10, 10/14 & 10/10/01

Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892

Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948

Other \_\_\_\_\_

## Office Action Summary

In a response of 7/26/02 to a restriction requirement of 7/1/02, applicants elected Group II claims 15-26 and 28-36 with traverse. In the traverse, applicants urge that claim 1 of Group I requires removing an organic solvent. However, in Group II, an organic solvent is not required and then removed. While an organic solvent is produced as a by-product in claim 24, the organic solvent is not required to be removed. Additionally, in claim 1, the organic solvent is not required to be a by-product from hydrolysis. The organic solvent in claim 1 can be added. Therefore, Groups I and II are distinct requiring substantial additional burden to examine both groups together, and the restriction requirement is adhered to and made final.

Claims 1-14 and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10 filed 7/26/02.

Claims examined on the merits are 15-26 and 28-36.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "abundant enough" recited in line 1 of each claim is uncertain as to meaning and scope. Being abundant enough is relative and subjective.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

5 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by Pope (5,693,513) or (5,739,020) or Hino et al (4,148,689) or Uo et al (AL 10 10 on 1449 of 2/20/01).

The claims requires a gel containing a solid network formed by condensation of hydroxy metallates from a sol solution wherein a cell is added to the sol solution to immobilize the cell in the network.

Pope, Hino et al and Uo et al each disclose hydrolyzing an 15 alkoxy silane to form a sol, adding cells to the sol and gelling the sol to obtain a gel with the cells immobilized therein.

The gel containing immobilized cells produced by Pope, Hino et al or Uo et al inherently has a solid network and is the same as the presently claimed gel.

20 Claims 15, 16, 21, 26 and 29-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Uo et al.

The claims are drawn to a sol containing a hydroxy metallate, water, sufficient dispersant to form macropores, and a biological material, to a method of producing a gel having macropores from the sol and to a gel 25 having macropores resulting from gelling the sol.

Uo et al disclose immobilization of yeast cells in a porous silica carrier with the sol-gel process by forming a mixture containing TMOS,

water, and PEG, hydrolyzing to form a sol, adding yeast pores, and forming a gel. See paragraph 2.3 on page 427. The porous gel can have pore diameters ranging from 0.1  $\mu\text{m}$  to 10  $\mu\text{m}$  which are macropores (page 429, paragraph 4).

5       The sol, process and gel disclosed by Uo et al are the same as presently claimed. The gel obtained by Uo et al will inherently have an amount of macropores as required by claims 31-35.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10       (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15       This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 20 25 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uo et al.

Providing a means for functionalizing the gel as in claim 20 and adding nutrients to the sol as in claim 22 would have been obvious 30 matters of choice within the skill of the art since it is well known to

functionalize a silica carrier to immobilize a biological material, and the addition of nutrients to the sol would have been expected to result in better growth of the cells.

Claims 17-19, 23 and 25 are rejected under 35 U.S.C. 103(a) as being 5 unpatentable over Uo et al in view of Klein et al (EJ on 1449 of 12/10/01) and Rao et al (AR on 1449 of 2/20/01).

The claims require a certain proportion of water.

Klein et al disclose the effect of water on hydrolysis of TEOS and Rao et al disclose the influence ratios of precursor, catalyst, solvent 10 and water on properties of silica aerogels.

It would have been a matter of obvious choice and require only limited routine experimentation to select a preferred optimum amount of water in Uo et al in view of the disclosures of Klein et al and Rao et al as to the effect of varying the water content.

15 Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 17-19, 23 and 25 above, and further in view of Schmidt et al (AV on 1449 of 2/20/01).

The claim requires an organic solvent to be produced as a by-product of hydrolysis.

20 Schmidt et al disclose that hydrolysis of alkoxy silanes produces an alcohol.

It would have been obvious that hydrolysis in Uo et al would produce an alcohol as taught by Schmidt et al.

Claims 15, 16, 20-22, 26 and 28-36 are rejected under 35 U.S.C. 25 103(a) as being unpatentable over Pope (5,693,513) or (5,739,020) in view

of Uo et al and Nakanishi et al (6,207,098) or Kajihara et al (BN on 1449 of 10/11/01), and if necessary in further view of Hino et al.

The invention and references are described above except for Nakanishi et al and Kajihara et al.

5 Nakanishi et al disclose forming a gel having macropores by adding a water soluble polymer to a silicon alkoxide, hydrolyzing to form a sol and gelling.

Kajihara et al disclose forming macropores in a titania film by adding PEG in a sol-gel process.

10 When producing a gel containing cells as disclosed by Pope, it would have been obvious to add a polymer as suggested by Uo et al and Nakanishi et al or Kajihara et al to provide macropores to obtain the expected function of such pores providing better access of nutrients to cells in the gel. The conditions of dependent claims would have been matters of 15 optimization well within the skill of the art. If needed, Hino et al would have further suggested conditions for producing a sol and gelling the sol.

Claims 17-19, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 15, 16, 20-22, 26 20 and 28-36 above, and further in view of Klein et al and Rao et al for reasons set forth above when applying these references.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 17-19, 23 and 25 above, and further in view of Schmidt et al for reasons set forth above when 25 applying this reference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

20 DMN  
10/11/02

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1651